UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: RANBAXY GENERIC DRUG APPLICATION ANTITRUST LITIGATION	CIVIL ACTION No. 19-md-02878-NMG

ORDER ON PLAINTIFFS MEIJER, INC. AND MEIJER DISTRIBUTION, INC.'S MOTION TO COMPEL NOVARTIS PHARMACEUTICALS CORPORATION (#201).

KELLEY, U.S.M.J.

I. Introduction.

Plaintiffs move to compel Novartis Pharmaceuticals Corporation (NPC) to produce documents requested in a third-party subpoena served on NPC on November 1, 2016.[1] NPC is the producer of a drug, branded Diovan (valsartan), that figures in the underlying litigation.[2] Plaintiffs and NPC have negotiated the production of certain documents, but are at an impasse on

[1] The parties have taken years to resolve disputes concerning the subpoena in part because Ranbaxy Inc. petitioned the First Circuit for leave to file an interlocutory appeal of this court's September 7, 2016 order denying Ranbaxy's motion to dismiss, *see Meijer, Inc. v. Ranbaxy Inc.*, 15-cv-11828-NMG, docket no. 80, discovery was stayed pending resolution of the petition, *see id.* at docket no. 133, and the matter was pending before the First Circuit for over two years, until December 28, 2018, when the petition was denied. *See Meijer, Inc., et al. v. Ranbaxy Inc., et al.*, 17-8008.

[2] Valsartan is "an angiotension II receptor antagonist… approved by the FDA for the treatment of hypertension and heart failure, as well as to reduce cardiovascular mortality in patients with problems of the left ventricle of the heart following myocardial infarction." *Meijer, Inc., v. Ranbaxy Inc.*, 15-cv-11828-NMG, 2016 WL 4697331, at *6 (D. Mass. June 16, 2016), *report and recommendation adopted* (Sept. 7, 2016). For simplicity, the generic version of this drug is referred to here as "generic Diovan."

two items: (1) NPC's profit margins for Diovan and (2) NPC's forecasts regarding an authorized generic product launch in September 2012. (#221 at 6.)[3] Oral argument was held on July 8, 2020. (#239.) The motion is fully briefed (##202 (redacted), 202-1 (unredacted, under seal), 221, 242, 243) and is ready for disposition.

II. Facts.

In a report and recommendation on Ranbaxy's motion to dismiss, this court set out at length the facts and the statutory and regulatory provisions relevant to the underlying case, *see Meijer, Inc., v. Ranbaxy Inc*., 15-cv-11828-NMG, 2016 WL 4697331, at **1-4 (D. Mass. June 16, 2016), *report and recommendation adopted* (Sept. 7, 2016), and will not repeat that information here, except as necessary to put the present discovery dispute in context.

In the underlying case, plaintiffs claim that Ranbaxy, a generic drug manufacturer, fraudulently obtained first-to-file generic exclusivity from the Federal Food and Drug Administration (FDA) for three drugs, including generic Diovan. (#202 at 7.) The wrongfully-obtained exclusivities allowed Ranbaxy to block all other generic drug manufacturers from entering the market, causing consumers to pay supra-competitive prices for these drugs, in violation of the Sherman Act, 15 U.S.C. § 2. *Id*. In accordance with a settlement agreement reached in related patent litigation, Ranbaxy agreed not to launch generic Diovan until September 21, 2012, on expiration of the relevant product patent. *Id*. at 9. Due to "ongoing manufacturing deficiencies," however, Ranbaxy failed to obtain final approval from the FDA and launch on that date. *Id*. It did not launch until almost two years later, in July 2014. *Id*. NPC launched an authorized generic version of Diovan the following day. *Id*. On January 5, 2015,

[3] All page numbers cited are those assigned by ECF.

after Ranbaxy's 180-day exclusivity period ended, other generic manufacturers whose products had been approved by the FDA launched immediately. *Id*. at 9-10; 2016 WL 4697331, at *6.

III. The Motion to Compel.

Plaintiffs assert that NPC's profit margin data on Diovan "is an important input in Meijer's market power analysis." (#202 at 6.) They argue that the requested data is key to Meijer's "establish[ing] the first element of its monopolization claim by providing evidence that Ranbaxy's conduct had actual detrimental effects on the [generic Diovan] market." *Id*. They need to know the profit margin for Diovan because "[t]he supra-competitive prices that purchasers paid for Diovan, as demonstrated by NPC's outsized profit margins, will show that the lack of price competition due to Ranbaxy's bottleneck resulted in overcharges for purchasers." *Id*.

Plaintiffs argue that NPC's forecasts concerning launching a generic in 2012 "will inform Meijer's causation scenarios, in addition to the analysis of antitrust impact and damages." *Id*. The forecasts will show the quantities of generic Diovan that NPC planned to produce, "the prices it planned to charge, and NPC's view of the drug(s) against which it competed." *Id*. NPC's forecasts will be particularly helpful since NPC was "a knowledgeable market participant with $2 billion in revenues at stake," and had an informed view of the prices that would have been charged based on the number of competitors, and of matters "concerning cross price elasticity between [generic Diovan] and other molecules (an important input for relevant market analysis)." *Id*. at 6-7.

In sum, plaintiffs assert that the documents in dispute, which "relate to a drug that has been off patent for almost eight years," are "highly relevant, easily collected, and not obtainable

from any party to the case." *Id*. at 7. Finally, the documents would be protected by the rigorous protective order in this case, that would limit review to "outside attorneys only." *Id*.

NPC objects to producing the materials, claiming that its profit margin data is "a closely guarded trade secret" and is irrelevant to plaintiffs' claims. (#221 at 6, 12.) NPC asserts that plaintiffs did not even bring up the issue of profit margin data until three years after serving the subpoena. *Id*. The information sought is irrelevant because plaintiffs seek it to support a novel theory that Ranbaxy's market power "somehow derives from market power allegedly enjoyed by *NPC's* branded Diovan," a theory unsupported by the law. *Id*. at 6-7 (emphasis in original). "If highly sensitive profit margins are relevant to the market power inquiry at all, it is *Defendant Ranbaxy's* margins that should be examined, not those of non-party NPC." *Id*. at 7 (emphasis in original).

NPC further argues that its forecasts concerning what would have happened if it had launched a generic version of Diovan in September 2012 are not probative, because they "reflect NPC's planning and uncertain projections of what could happen in certain scenarios," while plaintiffs have "real world data regarding what actually happened upon generic entry in the marketplace" that they can use to support their case. *Id*. at 7-8.

IV. The Law.

Third-party subpoenas issued in civil cases in federal court are governed by Federal Rule of Civil Procedure 45. "'A Rule 45 subpoena must fall within the scope of proper discovery under Fed. R. Civ. P. 26(b)(1).'" *Green v. Cosby*, 152 F. Supp.3d 31, 34 (D. Mass. 2015), *modified on reconsideration,* 160 F. Supp.3d 431 (D. Mass. 2016) (quoting *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, No. MDL 13–2419, 2013 WL 6058483, at *4 (D. Mass. Nov. 13, 2013)). Federal Rule of Civil Procedure 26(b)(1) provides

that parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and is proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1). While the Rule "generally permits liberal discovery of relevant information," *see Cumby v. Am. Med. Response, Inc*., No. 3:18-cv-30050-MGM, 2019 WL 1118103, at *3 (D. Mass. Mar. 11, 2019) (citations omitted), the scope of discovery is not unlimited, and the court must restrict discovery that is "unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive," or is outside the scope of discovery permitted by Rule 26(b)(1). Fed. R. Civ. P. 26(b)(2)(C).

A court may quash or modify a subpoena under Rule 45 if it requires the recipient to "disclos[e] a trade secret or other confidential research, development, or commercial information." Fed. R. Civ. P. 45(d)(3)(B)(i). The court may order production of material that requires the recipient to disclose trade secrets or other confidential information under specified conditions, if the serving party "shows a substantial need for the . . . material that cannot be otherwise met without undue hardship." Fed. R. Civ. P. 45(d)(3)(C)(i).

IV. Analysis.

The court allows plaintiffs' motion. At the outset, the court rejects two of NPC's objections to producing the documents: first, that production would be unduly burdensome and second, that plaintiffs did not press their request for margin data until November 2019, after the parties had engaged in negotiations for some time. The court finds that NPC is a large, sophisticated company and that locating and producing the requested documents, even though they date back some years, is not unduly burdensome. The effort NPC will expend in producing the documents is proportional to the needs of the case, given the documents' relevance to the claims "in this potentially multi-billion-dollar case." (#242 at 4.) With regard to plaintiffs' late

demand for margin data, the court finds that margin data was requested in the subpoena, *see* #203-1, and there is no indication that plaintiffs' delay in not specifically pressing for it until November 2019 was in bad faith.[4]

A. Profit Margin Data.

Balancing all the facts and circumstances here, the court finds that plaintiffs have met the requirement of Rule 45, to show a "substantial need" for margin data that "cannot otherwise be met without undue hardship." Fed. R. Civ. P. 45(d)(3)(C)(i). Although NPC makes a convincing case that its profit margin data qualifies for trade secret protection, or at least, that it is confidential commercial information under Rule 45, (#221 at 17-18), the material will be protected by the two-tier protective order in this case that limits review of the information to outside-attorneys only.

The court rejects NPC's argument that the requested information is not relevant to plaintiffs' claims and agrees with plaintiffs that "NPC's profit margin data will be a key component of Meijer's monopolization claim against Ranbaxy." (#202 at 16.) To make out a violation of section 2 of the Sherman Act, a plaintiff must show that a defendant had monopoly power in the relevant market, and that defendant acquired or maintained that power by improper means. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *In re: Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7 (1st Cir. 2020). The purpose of "inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition[.]" *F.T.C. v. Indiana Fed'n of Dentists*, 476 U.S. 447,

[4] In an email from plaintiffs' counsel to counsel for NPC in November 2019, plaintiffs' counsel explained that as plaintiffs began their analyses in the case, "including the analysis of the relevant market," it became clear to plaintiffs that their experts needed the information sought. (#203-7 at 2.)

460-61 (1986), citing 7 P. Areeda, *Antitrust Law* ¶ 1511, p. 429 (1986)). Market power is shown through either direct evidence of the control of prices or the exclusion of competition, or circumstantial evidence showing that the defendant had a dominant share in a well-defined relevant market. *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996).

Plaintiffs assert that "[m]arket power and the relevant market will be highly contested issues in this case." (#202 at 16.) Plaintiffs seek to show that when Ranbaxy blocked all generics from entering in 2012, consumers were forced to pay supra-competitive prices for brand Diovan, resulting in financial harm to consumers. NPC's margin data is relevant to this effort. Experts in pharmaceutical antitrust cases often rely on profit margin data to determine whether a company had the ability to charge supra-competitive prices. *See, e.g.*, *In re Solodyn (Minocycline Hydrocholoride) Antitrust Litig.*, Civil Action No. 14-md-02503, 2018 WL 563144, at *10 (D. Mass. Jan. 25, 2018).

NPC argues that plaintiffs' intention to rely on NPC's market power to establish their case has no basis in the law, as the caselaw speaks only to defendants' profit margins, not third-parties' margins. (#221 at 7.) This argument, however, does not take into account the unusual fact situation here, where plaintiffs claim that Ranbaxy's conduct in wrongly extending not its own market power, but NPC's market power over Diovan, from September 2012 to July 2014, denied purchasers the opportunity to buy lower-cost generics. Thus, it is NPC's market power that is at issue, not Ranbaxy's, and NPC's margins are direct evidence of its market power. *See Coastal Fuels*, 79 F.3d at 196-97.

The court rejects NPC's argument that plaintiffs should calculate the harm to competition by using Ranbaxy's margin information from 2014, when Ranbaxy sold generic Diovan during

its 180-day exclusivity period. (#221 at 19; #243 at 1.) The problem with this argument is that plaintiffs seek to determine the harm to consumers from 2012 to 2014, and Ranbaxy did not have any sales during this period.

B. Forecasts.

The court grants plaintiffs' motion with regard to NPC's forecasts concerning its planned 2012 launch of generic Diovan. This material will also be protected by the existing protective order. Contrary to NPC's argument, plaintiffs cannot use Ranbaxy's data from the launch of generic Diovan in 2014 as a substitute for this material, because, as plaintiffs argue, there are substantial differences between what actually happened when Ranbaxy entered the market in 2014, and what would have happened if Ranbaxy had not delayed entry of other generics for so long. (#242 at 3.) NPC's forecasts, while certainly speculative, are nevertheless bound to be well-informed, as NPC had great interest in maintaining their accuracy. *See In re Loestrin 24 FE Antitrust Litig.*, MDL No. 13-2472-WES-PAS, 2019 WL 3214257, at *6 (D.R.I. July 2, 2019). The forecasts are relevant to calculating the impact of varying numbers of generic entrants and damages, and will establish NPC's plans concerning meeting the potential launch of generics starting in 2012 with its own launch of an authorized generic.

V. Conclusion.

For the reasons set out above, plaintiffs' motion to compel (#201) is granted.

September 8, 2020.

/s/ M. Page Kelley
M. Page Kelley
Chief United States Magistrate Judge